

CLAIMS

We claim:

1. A method of detecting the formulation orientation of a multi-layer capsule-shaped tablet, the method comprising the steps of:

5 detecting the color at a spot location on a side of the tablet corresponding to one or another formulation layer depending on the formulation orientation of the tablet, wherein at least one of the one or another formulation layers contains a colorant; and

10 determining the formulation orientation of the tablet on the basis of the color detected.

2. A method of detecting the formulation orientation of a multi-layer capsule-shaped tablet, the method comprising the steps of:

15 detecting the color at a spot location on a side of the tablet corresponding to one or another formulation layer depending on the formulation orientation of the tablet, wherein at least one of the one or another formulation layers contains a dark colorant; and

20 determining the formulation orientation of the tablet on the basis of the color detected.

3. A method of detecting the formulation orientation of a multi-layer capsule-shaped tablet, the method comprising the steps of:

25 detecting the color at a spot location on a side of the tablet corresponding to one or another formulation layer depending on the formulation orientation of the tablet, wherein at least one of the one or another formulation layers contains a dark colorant and another formulation layer contains a light colorant; and

determining the formulation orientation of the tablet on the basis of the color detected.

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4. A method of detecting the formulation orientation of a multi-layer capsule-shaped tablet having an end portion containing a formulation layer that contains a drug ingredient and having an opposite end portion containing a formulation layer without a drug ingredient, the method comprising the steps of:

detecting the color at a spot location on a side of the tablet corresponding to one or another formulation layer depending on the formulation orientation of the tablet, wherein at least one of the one or another formulation layers contains a colorant; and

determining the formulation orientation of the tablet on the basis of the color detected.

5. A method of detecting the formulation orientation of a multi-layer capsule-shaped tablet having an end portion containing a formulation layer that contains a drug ingredient and having an opposite end portion containing a formulation layer without a drug ingredient, the method comprising the steps of:

detecting the color at a spot location on a side of the tablet corresponding to one or another formulation layer depending on the formulation orientation of the tablet, wherein at least one formulation layer without a drug ingredient contains a dark colorant; and

determining the formulation orientation of the tablet on the basis of the color detected.

6. A method of detecting the formulation orientation of a multi-layer capsule-shaped tablet having an end portion containing a formulation layer that contains a drug ingredient and having an opposite end portion containing a formulation layer without a drug ingredient, the method comprising the steps of:

detecting the color at a spot location on a side of the tablet corresponding to one or another formulation layer depending on the

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formulation orientation of the tablet, wherein a formulation layer without a drug ingredient contains a dark colorant and another formulation layer that contains a drug ingredient contains a light colorant; and

5 determining the formulation orientation of the tablet on the basis of the color detected.

7. A method of detecting the formulation orientation of a multi-layer capsule-shaped tablet having an end portion containing a dispensable formulation-forming layer and having an opposite end portion containing an expanding polymer formulation layer, the method comprising the steps of:

10 detecting the color at a spot location on a side of the tablet corresponding to one or another formulation layer depending on the formulation orientation of the tablet, wherein at least one of the one or another formulation layers contains a colorant; and

15 determining the formulation orientation of the tablet on the basis of the color detected.

8. A method of detecting the formulation orientation of a multi-layer capsule-shaped tablet having an end portion containing a dispensable formulation-forming layer and having an opposite end portion containing an expanding polymer formulation layer, the method comprising the steps of:

20 detecting the color at a spot location on a side of the tablet corresponding to one or another formulation layer depending on the formulation orientation of the tablet, wherein at least one expanding polymer formulation layer contains a dark colorant; and

25 determining the formulation orientation of the tablet on the basis of the color detected.

9. A method of detecting the formulation orientation of a multi-layer capsule-shaped tablet having an end portion containing a dispensable

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formulation-forming layer and having an opposite end portion containing an expanding polymer formulation layer, the method comprising the steps of:

detecting the color at a spot location on a side of the tablet
corresponding to one or another formulation layer depending on the
5 formulation orientation of the tablet, wherein an expanding formulation layer
contains a dark colorant and a dispensable formulation-forming layer contains
a light colorant; and

determining the formulation orientation of the tablet on the basis of the
color detected.

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10. A method of detecting the formulation orientation of a three-
layer capsule-shaped tablet having an end portion containing a first
formulation layer that contains a drug ingredient, a middle portion containing a
second formulation layer that contains a drug ingredient, and an opposite end
15 portion containing a third formulation layer without a drug ingredient, the
method comprising the steps of:

including at least one colorant in one formulation layer of the tablet;

detecting the color at a spot location on a side of the tablet
corresponding to one or another differently-colored formulation layer
20 depending on the formulation orientation of the tablet; and

determining the formulation orientation of the tablet on the basis of the
color detected.

11. A method of detecting the formulation orientation of a three-
25 layer capsule-shaped tablet having an end portion containing a first
formulation layer that contains a drug ingredient, a middle portion containing a
second formulation layer that contains a drug ingredient, and an opposite end
portion containing a third formulation layer without a drug ingredient, the
method comprising the steps of:

30 including a first colorant in one of the first or second formulation layers
of the tablet;

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including a second colorant in the third formulation layer;
detecting the color at a spot location on a side of the tablet
corresponding to one or another differently-colored formulation layer
depending on the formulation orientation of the tablet; and
5 determining the formulation orientation of the tablet on the basis of the
color detected.

12. The method of claim 11 wherein said first colorant is light and
said second colorant is dark.

10 13. A method of detecting the formulation orientation of a three-
layer capsule-shaped tablet having an end portion containing a first
dispensable formulation layer, a middle portion containing a second
dispensable formulation layer, and an opposite end portion containing an
15 expandable polymer formulation layer, wherein at least one of the first and
second layers contains a drug ingredient, the method comprising the steps of:
including a first colorant in one of the first or second dispensable
formulation layers of the tablet;
including a second colorant in the third expandable polymer
20 formulation layer;
detecting the color at a spot location on a side of the tablet
corresponding to one or another differently-colored formulation layer
depending on the formulation orientation of the tablet; and
determining the formulation orientation of the tablet on the basis of the
25 color detected.

14. The method of claim 13 wherein said first colorant is light and
said second colorant is dark.

15. A method of preparing a multi-layer capsule-shaped tablet having a push end and a dispensing end for laser drilling of a delivery port in said dispensing end, the method comprising the steps of:

detecting the formulation orientation of the tablet by detecting the color
5 at a spot location on a side of the tablet corresponding to one or another
formulation layer depending on the formulation orientation of the tablet,
wherein at least one layer contains a colorant;

determining the formulation orientation of the tablet on the basis of the color detected;

10 passing the tablets through a tablet rectifier wherein the orientation of
any improperly oriented tablets is rectified and the orientation of any properly
oriented tablets is maintained; and

collecting the uniformly oriented tablets from said tablet rectifier for transportation to a laser drilling station.

16. The method of claim 15 wherein the colorant is a dark colorant.

17. The method of claim 16 wherein the formulation layer containing the dark colorant does not contain a drug ingredient and another formulation layer containing a drug ingredient also contains a light colorant.

18. A method of making a three-layer tablet that contains color indicators for detecting the formulation orientation of the tablet with a color detector directed at a spot location on a side of the tablet, the method comprising the steps of:

formulating a first layer formulation containing a drug ingredient and a second layer containing a drug ingredient, one of said first or second layers also containing a first colorant;

formulating a third layer formulation containing a second colorant that
30 is distinguishable by said color detector from said first colorant or from no
color and not containing any drug ingredient; and

compressing said first, second and third layers into a capsule-shaped tablet having said first layer formulation at one end and said third layer formulation at the other end and having said second layer in between such that the formulation orientation of the tablet can be determined by detecting the color at a spot location on a side of the tablet corresponding to one or another differently-colored formulation layer depending on the formulation orientation of the tablet.

19. The method of claim 18 wherein said first colorant is light and said second colorant is dark.

20. A method of making a three-layer tablet that contains color indicators for detecting the formulation orientation of the tablet with a color detector directed at a spot location on a side of the tablet, the method comprising the steps of:

formulating a first layer formulation containing a drug ingredient and not containing any colorant;

formulating a second layer formulation containing a drug ingredient and a first colorant, said first colorant being complementary to no color;

formulating a third layer formulation containing a second colorant that is distinguishable by said color detector from said first colorant or from no color and not containing any drug ingredient; and

compressing said first, second and third layers into a capsule-shaped tablet having said first layer formulation at one end and said third layer formulation at the other end and having said second layer in between such that the formulation orientation of the tablet can be determined by detecting the color at a spot location on a side of the tablet corresponding to one or another differently-colored formulation layer depending on the formulation orientation of the tablet.

— adding a first colorant to one formulation layer containing a drug ingredient to be positioned in the proximity of a dispensing end of the tablet, said first colorant being complementary to no color;

compressing the formulation layers into a capsule-shaped tablet such that the formulation orientation of the tablet can be determined by detecting the color at a spot location on a side of the tablet corresponding to one or another differently-colored formulation layer depending on the formulation orientation of the tablet.

22. A three-layer tablet that contains color indicators for detecting the formulation orientation of the tablet with a color detector directed at a spot location on a side of the tablet, the tablet comprising:

a first layer formulation containing a drug ingredient and a second layer containing a drug ingredient, one of said first or second layers also containing a first colorant;

a third layer formulation containing a second colorant that is distinguishable by said color detector from said first colorant or from no color and not containing any drug ingredient wherein said first, second and third layers are compressed into a capsule-shaped tablet having said first layer formulation at one end and said third layer formulation at the other end and having said second layer in between such that the formulation orientation of the tablet can be determined by detecting the color at a spot location on a

side of the tablet corresponding to one or another differently-colored formulation layer depending on the formulation orientation of the tablet.

23. The tablet of claim 22 wherein said first colorant is light and said
5 second colorant is dark.

24. The tablet of claim 23 further comprising a membrane
surrounding the compressed layers through which the first and second
colorant are detectable.

25. The tablet of claim 24 further comprising a delivery port drilled
into said membrane at a location proximate to said first layer.

26. The tablet of claim 25 further comprising a drug overcoat
15 applied onto the surface of the membrane.

27. A three-layer tablet that contains color indicators for detecting
the formulation orientation of the tablet with a color detector directed at a spot
location on a side of the tablet, the tablet comprising:

20 a first layer formulation containing a drug ingredient and not containing
any colorant;

a second layer formulation containing a drug ingredient and a first
colorant, said first colorant being complementary to no color;

25 a third layer formulation containing a second colorant that is
distinguishable by said color detector from said first colorant or from no color
and not containing any drug ingredient wherein said first, second and third
layers are compressed into a capsule-shaped tablet having said first layer
formulation at one end and said third layer formulation at the other end and
having said second layer in between such that the formulation orientation of
30 the tablet can be determined by detecting the color at a spot location on a

side of the tablet corresponding to one or another differently-colored formulation layer depending on the formulation orientation of the tablet.

28. The tablet of claim 27 wherein said first colorant is light and said
5 second colorant is dark.

29. The tablet of claim 28 further comprising a membrane
surrounding the compressed layers through which the first and second
colorant are detectable.

30. The tablet of claim 29 further comprising a delivery port drilled
10 into said membrane at a location proximate to said first layer.

31. The tablet of claim 30 further comprising a drug overcoat
15 applied onto the surface of the membrane.

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